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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of:  
CHANTAL AMALRIC et al

Group Art Unit: 1616  
Examiner: M. Lamm

Serial No.: 10/635,898

Filed: August 7, 2003

For: NOVEL TOPICAL COMPOSITIONS WITH AN OILY OUTER PHASE AND  
PROCESS FOR THEIR PREPARATION

DECLARATION OF CHANTAL AMALRIC UNDER 37 CFR § 1.132

Honorable Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

Sir:

I, Chantal AMALRIC, do hereby declare as follows:

I am a named inventor of the above-identified patent application.

I am a pharmacist by training and also highly experienced in cosmetic formulation. I have been working in the cosmetics industry since 1984 and I have been working for the assignee in the above-identified application, Seppic, as manager of the applied cosmetics research team since 1989. During this period I have contributed to 26 patents filed mostly in France, with regular extension to the rest of Europe and the United States.

I am familiar with the Office Actions received during the prosecution the above-identified patent application, and I am familiar with the English language and am specifically aware of the contents of the outstanding Office Action dated December 12, 2005.

The present patent application discloses and claims topical sunscreen compositions, these compositions comprising a three-phase emulsion with two aqueous inner phases, one of which is an aqueous gel, and an oily external phase. At least one of the three separate phases contains a sunscreen filter.

In a concurrently filed amendment, independent claims 19 and 29 have been amended to incorporate the recitations of claim 40, specifying the preferred polymer in the gel phase as being selected from the group consisting of homopolymers and copolymers of acrylic acid, acrylic acid derivatives, acrylamide, acrylamide derivatives and acrylamidomethanepropanesulfonic acid.

In the currently pending Office Action dated December 12, 2005, claim 40 was rejected under 35 USC 103(a) as being obvious over Briggs et al. (WO 96/04894) in view of Nadaud et al. (US 5,798,108). The Examiner, in section 6 on page 6 of the currently pending Office Action) states that one having ordinary skill in the art would "have a reasonable expectation of obtaining the same gelling effect" using polymers in the Applicants' preferred list, some of which are disclosed in the secondary Nadaud et al reference, but not in the primary Briggs reference. It is concluded that using polymers as disclosed in the secondary reference in the type of emulsion described in the primary reference is "obvious absent a clear showing of unexpected results attributable to the applicant's specific selection."

As will be demonstrated in the results below, we have found, in tests carried out in our laboratories and under my supervision, that only gelifying polymers within the group now recited in the independent claims of the present application allow, with emulsions according to the invention, water-in-oil emulsions (not oil-in-water emulsions) to be obtained which are stable over time despite the use of minimal amounts of (external) oil phase compared to the (internal) aqueous phase.

The chosen group of polymers do therefore provide "unexpected results," going beyond the simple thickening role which could have been expected of them from the prior art, namely they stabilize particular types of emulsion in which the oil phase remains the external phase (within which aqueous droplets are dispersed) despite constituting less than 20% (even as little as 10%) of the overall emulsion.

The two series of experiments presented here show: 1) that various representative polymers within the chosen group provide stable water-in-oil (W/O) emulsions at high water contents; and 2) other thickening polymers, including all those indicated in the primary Briggs reference, cannot provide the effect sought after in this context.

1) Ability of homopolymers and copolymers of acrylic acid, acrylic acid derivatives, acrylamide, acrylamide derivatives and acrylamidomethanepropanesulfonic acid to form stable W/O emulsions

The following test results illustrate the capacity of various polymers materials falling within the group now claimed to give rise to water-in-oil emulsions even with a very small amount of oily external phase (10% or 15% by weight).

General method: The emulsions were obtained the method described in Example 1 of the present application, using a variable amount x % by weight of water-in-oil (W/O) primary emulsion and aqueous gel qs 100%.

The water-in-oil primary emulsion is composed as follows (overall 50:50 by weight of aqueous and oily phases):

Caprylic capric triglyceride	40 %
Fluidanov® 20X (alkylpolyxyloside based on 2-octyldodecanol, manufactured according to patent application EP-A-1142901)	8 %

PEG45 dodecyl glycol copolymer	2 %
Glycerin	5 %
SEPICIDE® HB (preservative)	1 %
MgSO <sub>4</sub> .7H <sub>2</sub> O	0.7 %
Water	qs 100 %

The aqueous gel (with which the primary emulsion is combined to produce the final product) is composed as follows:

Polymer	y %
SEPICIDE® CI (preservative)	0.2 %
Water	qs 100 %

Various emulsions were prepared using different amounts (x %) of W/O primary emulsion and different concentrations (y %) of gelling polymer in the aqueous gel. The table on the following page gives the type of emulsion obtained (W/O or O/W), and viscosity of the final emulsion in Pa.s (N.B. 1 Pa.s = 1000 mPas.s = 1000 cPs), for various values of x and y and for various polymers within the Applicant's preferred group (now specifically claimed):

x % (% of primary emulsion dispersed in the aqueous gel)	20 %	30 %
<b>Final composition</b>		
% bound water	80 %	70 %
% micronized water	10 %	15 %
% oily external phase	10 %	15 %
<b>Nature and amount of polymer in aqueous gel</b>		
SIMULGEL® NS, y = 3% (AMPS/Hydroxyethylacrylate copolymer)	W/O (90 Pa.s)	W/O (32 Pa.s)
SIMULGEL® EG, y = 2% (acrylic acid/AMPS copolymer)	W/O	W/O

+		
Carbomer®, y = 0.2% (polyacrylic acid)	(120 Pa.s)	(42 Pa.s)
Carbomer®, y = 0.4% (polyacrylic acid)	W/O (260 Pa.s)	W/O (135 Pa.s)
SEPIGEL® 305, y = 2% (acrylamide/AMPS copolymer)	W/O (33 Pa.s)	W/O (22 Pa.s)
SIMULGEL® EG, y = 3% (acrylic acid/AMPS copolymer)	W/O (77 Pa.s)	W/O (76 Pa.s)

These results show that W/O emulsions can be obtained at very low oily phase levels, for various gelling polymers within the Applicant's preferred group, including the case where a polyacrylic acid homopolymer is used.

2) Inability of any of thickening polymers of primary Briggs reference to form stable W/O emulsions according to the present invention at low oily phase levels

The primary Briggs reference (WO 96/04894), held up to now by the Examiner against the patentability of the present application, mentions (in the first paragraph of page 15) a number of conventional polymers that can be used to thicken aqueous phases in cosmetic preparations.

However, the present Applicant has found that, when it is desired to produce W/O emulsions with low amounts of oil phase (which is naturally difficult, because the less the amount is of the oil phase, the less tendency it will have to be the external continuous phase in which the internal aqueous phase is dispersed), the W/O emulsions being prepared so as to have two internal aqueous phases of which (only) one is a gel, none of the conventional polymers listed in Briggs can produce stable W/O emulsions.

The following comparative tests were carried out using a weight ratio of 20% primary emulsion : 80% aqueous gel. Approximately one half of the weight of the primary emulsion is constituted by the oil-phase ingredients (i.e. the C8-C10

triglyceride as principal oily material plus lipophilic emulsifiers). Consequently, only about 10% by weight of the final emulsion is constituted by the oil phase. This is an extremely low amount for a water-in-oil emulsion (with an oily outer phase). It is very useful to be able to prepare such emulsions, since although having an oily outer phase improves contact and spreadability on skin, too high a quantity of oily phase components can lead to a disagreeable feeling on the skin.

General method: The emulsions were obtained the method described in Example 1 of the present application, i.e. the oil phase components and aqueous phase not containing a thickening polymer are mixed to form a "primary emulsion", and then this primary emulsion is combined with a second aqueous phase, this time containing a thickening polymer, to produce a final emulsion.

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Composition	1	2	3	4	5	6	7
<b>Primary emulsion</b>							
APX Isofol 18 <sup>1</sup>	8 %	8 %	8 %	8 %	8 %	8 %	8 %
C8-C10 triglyceride	40 %	40 %	40 %	40 %	40 %	40 %	40 %
Sepicide® HB	1 %	1 %	1 %	1 %	1 %	1 %	1 %
Elfacos® ST9	2 %	2 %	2 %	2 %	2 %	2 %	2 %
Water	qs 100%	qs 100%	qs 100%	qs 100%	qs 100%	qs 100%	qs 100%
MgSO <sub>4</sub> .7H <sub>2</sub> O	0.7 %	0.7 %	0.7 %	0.7 %	0.7 %	0.7 %	0.7 %
Glycerin	5 %	5 %	5 %	5 %	5 %	5 %	5 %
<b>Aqueous gel</b>							
Hydroxyethyl cellulose	1 %						
Xanthan gum		1 %					
Simulgel® EG <sup>2</sup>			1 %	2 %			
Luviskol K30 (polyvinylpyrrolidone)					5 %		
Polymer jr400 <sup>3</sup>						1 %	
Poval® 217 (polyvinylalcohol)							5 %
Sepicide® CI	0.2 %	0.2 %	0.2 %	0.2 %	0.2 %	0.2 %	0.2 %
Water	qs 100%	qs 100%	qs 100%	qs 100%	qs 100%	qs 100%	qs 100%
<b>Type of emulsion produced (O/W or W/O) (by conductimetry)</b>							
	O/W	O/W	W/O	W/O	Phase separation	Phase separation	O/W

<sup>1</sup> APX isofol 18 is a composition of 2-octyl dodecanol-1 and 2-octyl dodecanol-1 polyxyloside

<sup>2</sup> Simulgel EG is an acrylamidomethylpropanesulfonic sodium salt/acrylic acid sodium salt copolymer

<sup>3</sup> JR 400 is the common name in cosmetic science of the polymer otherwise known as Polyquaternium 10, a cellulose, 2-hydroxyethyl 2-hydroxy-3-(trimethylammonio) propyl ether, chloride

As can be seen from the results in the table, at very low amounts of oil phase, although a polymer according to the claims as now amended, such as SIMULGEL® EG, gives rise to a water-in-oil emulsion (with two separate aqueous internal phases), other thickening polymers cannot give rise to stable water-in-oil emulsions under these circumstances.

Thus, none of the conventional thickening polymers listed in the Briggs reference (cellulose ether derivatives, polyvinyl alcohol, polyvinylpyrrolidone or polyquaternium) can give rise to the effect sought after in the present invention. These polymers, though they are able, as a general property, to thicken aqueous phases, cannot stabilize water-in-oil emulsions at very low oil phase levels in the type of emulsion used in the present invention (two aqueous inner phases, of which only one is a gel).

This effect is certainly not taught or predictable from the primary Briggs reference. Although the secondary Nadaud et al reference (US 5,798,108) mentions polymers within the group we prefer, the Nadaud et al reference does not teach or suggest the effect we have found. On the contrary, the Nadaud et al reference is specifically directed to W/O/W triple emulsions with a gelled continuous external aqueous phase. Our technology relates specifically to an external oil phase, which in the cosmetic field is quite distinct in terms of the effect on the wearer's skin, as well as in terms of water resistance, stability vis-à-vis air oxidation etc. A document teaching the use of certain gelling agents for emulsions with an aqueous external phase does not automatically suggest their use to a cosmetics specialist for emulsions with an oily external phase, and the Nadaud et al reference certainly does not teach or suggest the specific effects we have observed at low oil phase levels in oily external phase emulsions.

I hereby declare that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true; and further that these



statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

le 6 juin 2006

Date

Amalric

By: Chantal AMALRIC